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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/690,436	10/22/2003	Sharon Mi Lyn Tan	01194-513001 / 03-045	3696
26161	7590	01/09/2007		
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			EXAMINER THANH, LOAN H	
			ART UNIT 3763	PAPER NUMBER

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/09/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/690,436	<b>Applicant(s)</b> TAN, SHARON MI LYN	
	<b>Examiner</b> LoAn H. Thanh	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2006.  
 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.  
 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
 6) ☒ Claim(s) 1-26 is/are rejected.  
 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
 10) ☒ The drawing(s) filed on 24 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) ☐ All b) ☐ Some \* c) ☐ None of:  
 1. ☐ Certified copies of the priority documents have been received.  
 2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
 \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)  
 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
 Paper No(s)/Mail Date \_\_\_\_\_.  
 4) ☐ Interview Summary (PTO-413)  
 Paper No(s)/Mail Date. \_\_\_\_\_.  
 5) ☐ Notice of Informal Patent Application (PTO-152)  
 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

***Response to Amendment***

The formal replacement drawings filed 08/24/06 have been approved.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. (USPN 6,371,944) in view of Davidson (USPN 5,588,443) and further in view of Fischell et al. (USPN 5,413,561).

Liu et al. disclose a system for use in the body comprising a catheter 7, a side arm, a lumen through the side arm 9, which communicates with the catheter lumen and a one-way valve 5 and an intervention device such as the wire 18. Liu et al. however does not teach the wire to be coated with an antimicrobial agent. Davidson discloses a wire for use in the body, which is coated with antimicrobial, anticoagulants or, medicaments as desirable or for reducing adhesion or other adverse cellular or tissue response to surfaces in contact with blood. See column 4, lines 25-35. It would have been obvious to one of ordinary skill in the catheter art at the time the invention was made to modify the wire used to contact with blood of Liu et al. with an antimicrobial coating as taught by Davidson in order to prevent infections within the internal system of

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the patient. Liu et al. and Davidson in combination is silent to a cap coupled to the guidewire/intervention device. Fischell et al. teach a cap coupled to a guidewire in order to provide a handle or sealing at the port/luer end. It would have been obvious to one of ordinary skill in the art to modify the device of Liu et al. in view of Davidson with a cap as taught by Fischell et al. in order to provide a handle or sealing end to prevent contamination or leaking of fluids at the proximal end.

With respect to claims 7-9 and 16-18, Liu et al. in view of Davidson does not disclose a threaded or stopper cap with the rod affixed to the cap. Fischell et al. disclose a sealing cap 80 for sealing the system to reduce the blood loss when inserting guiding catheters/rods/wires. See figures 1-3 which discloses a stopper cap and figure 7 which disclose a threaded cap. It would have been obvious to one of ordinary skill in the medical art to modify the device of Liu et al. with an end cap for the side arm as taught by Fischell et al. in order to reduce blood loss when inserting the wire into the side arm.

With respect to claims 5 and 14, it is well known in the surgical and medical arts to prepare/swab a patient with iodine before injecting or surgically introducing a device into a patient. With that knowledge in mind, it would have been obvious to one of ordinary skill to swab/coat a device with iodine as a mere obvious selection of medicament which would prevent infection.

With respect to the claims 20-26, the intervention device is capable of performing the function of remaining in the catheter lumen during fluid flow. Further, it is also

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considered to be associated with a hemodialysis procedure lacking any structural distinguishing features. Injections and infusions are well known procedures which are associated with hemodialysis.

Claims 1-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu et al. (USPN 6,371,944) in view of Davidson (USPN 5,588,443) and further in view of Fields et al. (USPN 5,357,961).

Liu et al. and Davidson teaches the invention as substantially claimed. See above. However, they are silent to a cap connected to a guidewire/ intervention device. Fields et al. teach a guidewire/ intervention device having a cap for manipulation of the guidewire/intervention device ( see column 4, lines 66-column 5, lines 6) and for sealing against the port and for stopping the guidewire at a fixed location relative to the catheter. ( See column 4, lines 66-column 5, lines 6). It would have been obvious to one of ordinary skill in the art of handling guidewires to modify the guidewire/intervention device of Liu et al. and Davidson with a cap/handle as taught by Fields et al. in order to provide a larger gripping surface for manipulating and maneuvering the guidewire/ intervention device.

### ***Response to Arguments***

Applicant's arguments filed 06/05/06 have been fully considered but they are not persuasive since the Examiner is interpreting the claims in the broadest possible language. It is well known to interchangeably call a "catheter" a "needle" and vice versa. Further, structurally a needle is a tube and a catheter is a tube. Since the claim

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language does not structurally distinguish a catheter from a needle , it is the Examiner's position that the prior art still applies and anticipates the broad claim language.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

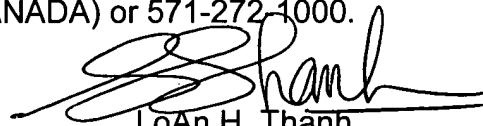
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (571) 272-4966. The examiner can normally be reached on Mon. - Fri. (First Friday off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on (571) 272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'LoAn H. Thanh', is written over a horizontal line.

LoAn H. Thanh  
Primary Examiner  
Art Unit 3763

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